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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,867	12/05/2001	Clifton A. Alfemess	1931-7-3	5299

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/011,867

Applicant(s)

ALFERNESS ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 3,12,21,31 and 42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-30 and 32-36 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,13-20,22,37-41 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

- 1) Figure 3 is the embodiment of the first species.
- 2) Figure 6 is the embodiment of the second species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 10, 19, 23 and 37 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of **all claims** readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Richard O. Gray, Jr. on 3/4/03 a provisional election was made without traverse to prosecute the invention of Species 1 (Figure 3), claims 1, 2, 4-11, 13-20, 22-30, 32-41 and 43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 12, 21, 31 and 42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

1. The specification is objected to because it is unclear from pages 11-12 how the method of effecting mitral valve annulus geometry can include the step of fixing a cable to the first anchor *after* fixing first and second anchors within the heart (paragraph [19]) and how the first anchor is provided with a cable extending proximally therefrom *after* deploying the first anchor in the coronary sinus (paragraph [21]). It appears from these pages 11-12 that the cable is already fixed to the first anchor prior to fixing of the first anchor. Applicant must clarify without adding new matter.

Claim Objections

2. Claims 18 and 39 are objected to because of the following informalities:

- ✓ a) Claim 18, line 1, --means-- should be inserted after "cable".
- ok → b) Claim 18, line 1, --a-- should be inserted after "includes".
- ✓ c) Claim 39, line 3, "dimension" should be changed to --dimensioned--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 20, 22, 37-41 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ 4. Claims 19 and 37 are indefinite because it is unclear from the specification on pages 11-12 how the method of effecting mitral valve annulus geometry can include the step of fixing a cable to the first anchor *after* fixing first and second anchors within the heart (claim 19) and how the first anchor is provided with a cable extending proximally therefrom *after* deploying the first anchor in the coronary sinus (claim 37). It appears from these pages that the cable is already fixed to the first anchor prior to fixing of the first anchor. Applicant must clarify without adding new matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2, 4-11, 13-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. (USPAP 2001/0018611 as cited in applicant's IDS) in view of Lashinski et al. (USPAP 2002/0151961).

Solem et al. discloses a device and method for effecting mitral valve annulus geometry of a heart with all the elements of claims 1, 10 and 19, but is silent to a lock that locks the cable on the second anchor. See abstract for placement within coronary sinus, Figures 12-13 and paragraph [0054] for the method (as interpreted by Examiner) and a first anchor (23), a cable (27) fixed to the first anchor and extending proximally therefrom, and a second anchor (25) positioned proximal to the first anchor and arranged to slidably receive the cable (through 33) such that the cable (27) spans between first and second anchors. Lashinski et al. teaches a device placed within the coronary sinus to remodel the mitral valve annulus wherein the device has a cable and a lock on the proximal end of the device (claims 7 and 16) in order to lock the cable to the device in a curved, remodeling configuration. See Figures 17B-17C and paragraph [0146] for a cable (365) and a lock including pawl (328) and ratchet assembly (368) (claims 8 and 17). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lashinski et al. to modify the device of Solem et al. to include a ratchet lock on the second anchor (proximal end of the device) so that the distance between first

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and second anchors can be reduced in a controlled manner to assume a remodeling configuration, and so that the cable can then be locked on the second anchor to maintain this remodeling configuration.

Solem et al. is also silent to the additional limitation of the cable including a coupling configured to releasably connect to a cable tension assembly, as required by claims 9, 18 and 22. Lashinski et al. teaches the cable (365) to include a coupling (367) configured to releasably connect to a cable tension assembly (combination of 366, 310, 312) in Figures 17B-17C in order for the cable tension assembly to move the cable proximally, which deflects the device to a remodeling configuration. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings Lashinski et al. to modify the device of Solem et al. to have the cable include a coupling configured to releasably connect to a cable tension assembly. By including this coupling to the device of Solem et al., Examiner contends that the cable tension assembly can be used again at a later time in the case that the distance between the anchors needs further shortening.

Claims 2, 11 and 20, see Figures 12-13 and paragraph [0054] for second anchor being configured to be positioned and fixed in the coronary sinus.

Claims 4, 5, 13 and 14, see paragraph [0070] and Figures 12-13 for device being deployed using a catheter. Since cable 27 is extending from and passing through first and second anchors respectively, it is highly unlikely that the anchors are balloon-expandable (not self-expanding) because the balloon used to inflate the anchors would interfere with and possibly damage the cable. Therefore, it would have been obvious to one of ordinary skill in the art to make the first and second anchors self-expanding.

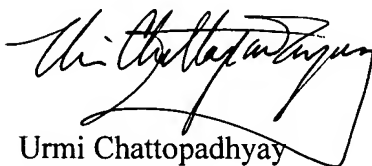
Claims 6 and 15, see paragraph [0022] for cable including a pressure distributor.

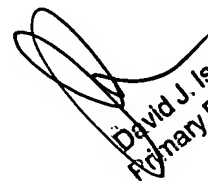
Allowable Subject Matter

7. Claims 23-30 and 32-36 are allowed.
8. Claim 37 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.
9. Claims 38-41 and 43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.


Urmi Chattopadhyay
Art Unit 3738


David J. Isabella
Primary Examiner

uc
March 5, 2003